

Applicants : Zhongyi Li, et al.  
Serial No. : 10/577,564  
Filed : April 27, 2006  
Page 10 of 19: Amendment in Response to July 23, 2009 Office Action

**Remarks**

Claims 1-18, 20, 24, 37 and 43 were pending in the subject application. By this Amendment, applicants have canceled claims 3, 5, 7, and 37 without disclaimer or prejudice to applicants' right to pursue the subject matter of these claims in a different application. Applicants have also amended claims 1, 2, 6, 12, 16, 17, 18, 20, 24 and 43, and added new claims 48-55.

Support for the amendments to claims 1, 18, 20, and 24 may be found in the subject specification, *inter alia*, on page 9, lines 28-32; page 25, lines 1-16; page 43, lines 1-12; page 25, line 29; page 26, lines 15-26 and line 31; page 21, lines 11-16; page 25, lines 22-24; page 11, lines 19-21; Figure 2; page 8, line 25; page 18, line 31; page 5, lines 24-25; and page 13, lines 33-25.

Support for the amendment to claim 12 may be found in the subject specification, *inter alia*, on page 17, lines 34-35.

Support for the amendment to claim 17 may be found in the subject specification, *inter alia*, on page 15, lines 34-34; page 16, lines 7-17; page 25, lines 1-16; page 43, lines 1-12; page 25, line 29; page 26, lines 15-26 and line 31; page 21, lines 11-16; page 25, lines 22-24; page 11, lines 19-21; Figure 2; page 8, line 25; page 18, line 31; page 5, lines 24-25; and page 13, lines 33-25.

Support for the amendment to claim 43 may be found in the subject specification, *inter alia*, on page 11, lines 7-9 and 19-21; Figure 2; page 26, lines 15-26 and line 31; page 21, lines 11-16; and page 25, lines 22-24.

Applicants : Zhongyi Li, et al.  
Serial No. : 10/577,564  
Filed : April 27, 2006  
Page 11 of 19: Amendment in Response to July 23, 2009 Office Action

Support for the new claim 48 may be found in the subject specification, *inter alia*, on page 34, lines 2-4.

Support for the new claim 49 may be found in the subject specification, *inter alia*, on page 9, lines 9-10.

Support for the new claim 50 may be found in the subject specification, *inter alia*, on page 34, lines 9-10.

Support for the new claim 51 may be found in the subject specification, *inter alia*, on page 34, lines 13-15.

Support for the new claim 52 may be found in the subject specification, *inter alia*, on page 34, lines 7-8.

Support for the new claim 53 may be found in the subject specification, *inter alia*, on page 34, lines 2-5.

Support for the new claim 54 may be found in the subject specification, *inter alia*, on page 34, lines 2-4.

Support for the new claim 55 may be found in the subject specification, *inter alia*, on page 8, line 25; and page 18, line 31.

Claims 2, 6 and 16 were amend for clarity,

Accordingly, claims 1, 2, 4, 6, 8-18, 20, 24, 43 and 48-55 are pending, of which claims 7, 15-18, 20 and 24 have been withdrawn pending allowance of the examined claims.

Applicants : Zhongyi Li, et al.  
Serial No. : 10/577,564  
Filed : April 27, 2006  
Page 12 of 19: Amendment in Response to July 23, 2009 Office Action

### **Specification**

On page 2 of the July 23, 2009 Office Action, the Examiner objected to the disclosure because it contained an embedded hyperlink and/or other form of browser executable code.

In response, applicants have amended the specification such that it no longer contains any embedded hyperlinks and/or other form of browser-executable code.

### **Rejection Under 35 U.S.C. §112, First Paragraph (Enablement)**

On page 2 of the July 23, 2009 Office Action, the Examiner rejected claim 1-6, 8-14 and 43 under 35 U.S.C. §112, first paragraph, alleging that the specification, while being enabling for the reduction of SBEIIa using specific sense and anti-sense construct for exons 1, 2 and 3 along with intron 3 on the sense orientation and exons 1, 2, 3 and 4 of the SBEIIa enzyme in the antisense orientation, does not reasonably provide enablement for any exogenous nucleic acids expressing any other inhibitors of SBEIIa and SBEIIb. The Examiner also alleged that the specification does not provide any guidance as to any other genetic variation leading to a reduced level of SBEIIa or SBEIIb.

### **Applicants' Reply**

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, and without conceding the correctness of the Examiner's position, applicants have herein amended the claims to recite a grain obtained from a rice plant comprising i) starch, ii) an exogenous nucleic acid molecule comprising nucleotides in a sequence which is the same as, or is fully complementary to, a sequence of at least 50 contiguous nucleotides of the starch

Applicants : Zhongyi Li, et al.  
Serial No. : 10/577,564  
Filed : April 27, 2006  
Page 13 of 19: Amendment in Response to July 23, 2009 Office Action

branching enzyme IIa (SBEIIa) gene coding region whose sequence is set forth in SEQ ID NO. 2 which inhibits expression of SBEIIa of a rice SBEIIa gene.

As amended, the claims recite an exogenous nucleic acid molecule which would reasonably be expected to silence the SBEIIa gene. Applicants note that the subject specification provides detailed techniques specific for reducing expression of the SBEIIa gene as currently claimed, as described, e.g. on pages 20-30. Applicants, for example, provide guidance for the design of a transgene for inactivation of the SBEIIa gene in rice using the sequence set forth in SEQ ID NO. 2, *inter alia*, on page 24, lines 1-32. The subject specification also teaches the preparation of SBEIIa duplex-RNA constructs on page 43, lines 14-32. The subject specification, further teaches on page 25, lines 28-30 and page 26, lines 30-32 the use of nucleic acid molecules of at least 50 nucleotides for effective gene silencing.

By teaching for the first time that inhibiting expression of the SBEIIa gene using exogenous nucleic acids specifically targeted to at least 50 nucleotides of SEQ ID NO. 2 results in an increase in amylose in the rice grain, applicants have provided all of the information that one of skill in the art needs to readily make and use the rice grain as claimed. Once in possession of applicants' disclosure, one of skill in the art needs only routine techniques to practice the invention as now claimed.

Practice of the invention as currently claimed requires no undue experimentation. There is no reason much less any evidence on the record to question enablement of the full

Applicants : Zhongyi Li, et al.  
Serial No. : 10/577,564  
Filed : April 27, 2006  
Page 14 of 19: Amendment in Response to July 23, 2009 Office Action

scope of the invention as now claimed. As stated in MPEP §2164.01(b):

"As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)."

Applicants' Examples are correlated to the full scope of the claims now pending by the specification.

Accordingly, as amended, the pending claims are enabled and the rejection should be withdrawn.

**Rejection Under 35 U.S.C. §112, First Paragraph (Written Description)**

On page 6 of the July 23, 2009 Office Action, the Examiner rejected claims 1-6, 8-14 and 43 under 35 U.S.C. §112, first paragraph, as allegedly not complying with the written description requirement.

**Applicants' Reply**

In response, applicants respectfully traverse the Examiner's rejection. However, in order to expedite prosecution, and without conceding the correctness of the Examiner's position, applicants have herein amended the claims to recite a grain obtained from a rice plant comprising i) starch, ii) an exogenous nucleic acid molecule comprising nucleotides in a sequence which is the same as, or is fully complementary to, a sequence of at least 50 contiguous nucleotides of the starch branching enzyme IIa (SBEIIa) gene coding region whose

Applicants : Zhongyi Li, et al.  
Serial No. : 10/577,564  
Filed : April 27, 2006  
Page 15 of 19: Amendment in Response to July 23, 2009 Office Action

sequence is set forth in SEQ ID NO. 2 which inhibits expression of SBEIIa of a rice SBEIIa gene.

Applicants note that the claimed subject matter is extensively described by the specification. For example, the specification discusses the cDNA and gene sequence of rice SBEIIa (SEQ ID No. 2). See, page 11, lines 19-21 and Fig. 2. Furthermore applicants describe the technique of gene inhibition, e.g. on pages 25-27 and 38-39 of the specification. Applicants also note that gene silencing techniques were known at the time of the applicants' filing date and were readily applicable to inhibit a specific gene whose sequence was known, e.g. the SBEIIa gene, whose sequence is presented in the subject application.

Applicants have described even more than the patent law requires. As set forth in the MPEP §2163,

"The description need only describe in detail that which is new or not conventional." See *Hybritech v. Monoclonal Antibodies*, 802 F.2d at 1384, 231 USPQ at 94; *Fonar Corp. v. General Electric Co.*, 107 F.3d at 1549, 41 USPQ2d at 1805 (source code description not required).

MPEP §2163 further states that,

"Information which is well known in the art need not be described in detail in the specification." See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

Applicants have described that which is new, i.e. that silencing the SBEIIa gene in rice grain results in an increase in amylose content in the rice grain. The multitude of ways

Applicants : Zhongyi Li, et al.  
Serial No. : 10/577,564  
Filed : April 27, 2006  
Page 16 of 19: Amendment in Response to July 23, 2009 Office Action

of silencing the SBEIIa gene were well known in the art by applicants' filing date

In light of the amendments to the claims, the disclosure of SEQ ID NO. 1, the described examples, and the established nature of gene silencing in plants by applicants' filing date, applicants maintain that it is untenable that one skilled in the art would not recognize applicants' possession of the invention as currently claimed and respectfully request the Examiner to reconsider and withdraw this rejection.

**Restriction Under 35 U.S.C. §103(a)**

On page 9 of the July 23, 2009 Office Action, the Examiner rejected claim 1-6, 8-14 and 43 under 35 U.S.C. §112, first paragraph, as allegedly unpatentable over Broglie et al. (U.S. Patent 6,376,749. Specifically, the Examiner contended that it would have been obvious to one of ordinary skills in the art to use the anti-sense construct taught by Broglie et al. as suggested by Broglie et al. to transform rice to modify the starch content of the rice.

**Applicants' Reply**

In response, applicants respectfully traverse the Examiner's rejection for reasons which follow. The Examiner's reasoning is primarily based on art showing the maize plants transformed with an antisense construct targeting the SBEIIb gene suppresses the expression of SBEIIb in corn and results in increased amylose content in corn.

First, applicants are claiming rice grain, not maize, comprising starch and an exogenous nucleic acid molecule which inhibits the expression of SBEIIa (not "b") and processes of

Applicants : Zhongyi Li, et al.  
Serial No. : 10/577,564  
Filed : April 27, 2006  
Page 17 of 19: Amendment in Response to July 23, 2009 Office Action

making them.

Second, Broglie et al. do not teach altering expression of the SBEIIa for any reason.

These first and second deficiencies of the rejection require that the rejection be withdrawn.

Furthermore, the Examiner acknowledged on page 9 of the July 23, 2009 Office that Broglie et al. do not teach a rice plant or grain transformed with an antisense construct. However, the Examiner alleged that "...Broglie et al does suggest the use of rice in paragraph 2 of the background of the inventions stating that starch isolated from rice may meet the functional requirements..." Applicants note that Broglie et al. do not suggest or teach transforming rice with an antisense sequence of the maize SBEIIb cDNA. Paragraph 2 of the section titled 'Background of the Invention' of Broglie et al. simply acknowledges that different plants produce different amylose/amylopectin ratios and that this ratio affects the physical and functional properties of starch, i.e. viscosity and stability of gelatinized starch. In regard to rice, Broglie et al. state "[w]here a specific function property is needed, starches obtained from various crops such as corn, rice, or potatoes may meet the functionality requirement." Broglie et al. further mention that if one cannot identify a crop that meets the function requirement, then "functionality can sometimes be achieved by chemically modifying the starch."

Even if applicants were claiming a method of transforming rice grain with the anti-sense sequence targeting SBEIIb, Broglie

Applicants : Zhongyi Li, et al.  
Serial No. : 10/577,564  
Filed : April 27, 2006  
Page 18 of 19: Amendment in Response to July 23, 2009 Office Action

et al. do not teach nor suggest transforming rice grain with an anti-sense maize SBEIIb cDNA.

Applicants further note that Tetlow et al. (cited by the Examiner on Form PTO-892 attached to the July 23, 2009 Office Action), reported that maize SBEIIa mutant displays no apparent alteration in the storage starch of the maize (page 2134, second column, of Tetlow et al.).

Based on the teachings of the prior art, one of skill in the art could not predict that targeting the SBEIIa gene would affect amylose content in the starch of rice grain. Applicants note that predictability is required in a proper obviousness rejection. See, e.g., *KSR Int'l. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (April 30, 2007).

Moreover, the prior art as evidenced by Tetlow et al., taught away from applicants' claimed invention. Specifically, the prior art taught that targeting the SBEIIa gene does not affect amylose content. Such a teaching away cannot be ignored, and supports the patentability of applicants' claimed invention. M.P.E.P. §2141.02.

For each of the foregoing reasons, the obviousness rejection is improper and should be withdrawn.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone at them number provided below.

Applicants : Zhongyi Li, et al.  
Serial No. : 10/577,564  
Filed : April 27, 2006  
Page 19 of 19: Amendment in Response to July 23, 2009 Office Action

No fee, other than the enclosed total fee of \$762.00, including a \$490.00 two-month extension of time fee, an excess claim fee of \$52.00 for one (1) claim in excess of twenty-five (25) total previously paid for, and an excess claim fee of \$220.00 for one (1) independent claim in excess of five (5) total previously paid for is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such additional fee to Deposit Account No. 03-3125.


Respectfully submitted,



John P. White  
Registration No. 28,678  
Gary J. Gershik  
Registration No. 39,992  
Attorneys for Applicants  
Cooper & Dunham LLP (Customer #23432)  
30 Rockefeller Plaza  
20<sup>th</sup> Floor  
New York, New York 10112  
(212) 278-0400

I hereby certify that this correspondence is being deposited on this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

  
Gary J. Gershik  
Reg. No. 39,992

12/22/09  
Date